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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/425,516	10/22/1999	GORDON J. FREEMAN	RPI-004C3CN	9657

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LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER

GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/22/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/425516	FREEMAN	
	Examiner	Art Unit	
	GAMBEL	1644	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 3/8/02, 8/20/02, 4/10/03

2a) ☒ This action is FINAL.      2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☐ Claim(s) \_\_\_\_\_ is/are pending in the application. 70-121

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration: 119-121

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed. 70-79, 81-90, 92-102, 104-114

6) ☐ Claim(s) \_\_\_\_\_ is/are rejected. 80, 91, 103, 115-118

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 8/18/02 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner. SEE OFFICE ACTION

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All   b) ☐ Some \*   c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☒ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____ 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____
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### DETAILED ACTION

1. Applicant's amendment, filed 3/8/02 (Paper No. 12), has been entered.  
Claims 63-64 and 68-69 have been canceled.  
Claim 72 has been added.

Applicant's amendment, filed 2/10/03 (Paper No. 16), has been entered.  
Claims 28 and 65-67 have been canceled.  
Claims 70-72 have been amended.  
Claims 73-121 have been added.

Claims 70-121 are pending in the instant application.

Newly added claims 119-121 have been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to a nonelected invention. Claims 119-121 are drawn to methods of inhibiting B7-2 interactions as well as inhibiting T cell proliferation and cytokine production with antibodies that bind SEQ ID NO: 23, which is the B7-1 specificity. Applicant's elected Group I, including the B7-2-specific antibody as the first agent and an agent that blocks the interaction of B7-1 with its natural ligand as the second agent in the claimed methods in Paper No. 9.

Claims 70-118 are under consideration in the instant application.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action. This Office Action will be in response to applicant's arguments, filed 3/8/02 (Paper No. 12). The rejections of record can be found in the previous Office Action (Paper No. ).
3. Applicant's assertions for the filing date of the instant claims, filed 3/8/02 (Paper No. 12), are acknowledged. However, it is noted that applicant's amendment, filed 2/10/03 (Paper No. 16), does not provide a similar analysis for newly added claims 73-121.

From a review of USSN 08/101,624, now U.S. Patent No. 5,942,607; it appears that applicant's instant claims 70-79, 81-90, 93-102, 105-114 have a filing date of 7/26/93. USSN 08/101,624, now U.S. Patent No. 5,942,607 does not appear to provide written support for antibodies produced from the hybridomas ATCC Accession Numbers HB 11686, 11687 and 11688 (claims 80, 91, 103 and 115) as well as "further comprising contacting the cell with an additional immunosuppressive agent, including an immunosuppressive drug" (claims 116-118).

If applicant disagrees, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the parent application..

In addition, applicant is invited to verify the priority date of the instant claims, including written support and enablement under 35 USC 112, first paragraph applicant is invited

Please see the enclosed form PTO-948.

#### INFORMATION ON HOW TO EFFECT DRAWING CHANGES

##### A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

##### B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

##### Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

5. Upon reconsideration of the recitation of the pending claims, the previous rejections, under 35 U.S.C. 112, first paragraph, enablement and written description have been withdrawn .

6. Claims 80, 91, 103 and 115 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that HB 11686, 11687 and 11688 antibodies / hybridomas are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the pertinent cell lines / hybridomas which produce these antibodies. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all

restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

7. Claims 80, 91, 103, 115 and 117-118 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 80, 91, 103 and 115 are indefinite in that the ATCC accession numbers refer to hybridomas HB 11686, 11687 and 11688 and not antibodies per se. Applicant is invited to amend the claims to include the recitation of "hybridomas"

B) Claims 117-118 lack proper antecedent basis for "agent". Applicant should amend the proper dependency to claim 116 and not claim 105.

C) Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

8. As pointed out above, applicant is invited to indicate the priority date of the instant claims 116-118. In the absence of a clear priority date, the following art rejections are set forth.

Claims 116-118 are rejected under 35 U.S.C. § 102(e) as being anticipated by de Boer et al. (U.S. Patent No. 5,747,034) (see entire document) for the reasons of record.

De Boer et al. teach methods of inhibiting immune responses both in vitro and in vivo with combinations of B7-specific inhibitors, including the use of both B7-1-specific and B7-2-specific antibodies (see entire document, including Columns 14-16, Compositions Including Immunosuppressive Agents and Formulations and Methods of Administration). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods of inhibiting immune responses with B7-specific antibodies and immunosuppressive agents.


9. Claims 70-79, 81-90, 91-102, 104-114 appear to be free of the prior art and deemed allowable.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

  
Phillip Gambel, PhD.  
Primary Examiner  
Technology Center 1600  
April 14, 2003